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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,947	03/08/2002	Anne Mette Wolff	WOLFF=3	7383

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EXAMINER	
LAMBERTSON, DAVID A	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,947	WOLFF ET AL.	
	Examiner	Art Unit	
	David A. Lambertson	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18 and 20-124* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-11, 28-39, 41-46, 63-74, 80-82, 84, 86-98, 103-107, 113-117, drawn to a generic isolated polynucleotide comprising a first nucleic acid encoding at least one regulator of morphology and a second nucleic acid sequence comprising an expression signal, vectors comprising said isolated polynucleotide, fungal host cells comprising said vector, and methods of making said fungal host cells, classified in class 536, subclass 23.1.

II. Claims 12-18, drawn to an isolated polynucleotide comprising a nucleic acid sequence comprising an expression signal sequence operably linked to residues 542-1930 of SEQ ID NO: 1 or fragments or variants thereof, classified in class 536, subclass 23.1.

III. Claims 20-27, drawn to an isolated polynucleotide comprising a nucleic acid sequence comprising an expression signal sequence operably linked to residues 534-2471 of SEQ ID NO: 11 or fragments or variants thereof, classified in class 536, subclass 23.1.

IV. Claims 47-50 and 99, drawn to an isolated polynucleotide comprising residues 1-741 of SEQ ID NO: 9 operably linked to a nucleic acid sequence encoding at least one regulator of morphology, and dimorphic fungal cells containing said polynucleotide, classified in class 536, subclass 24.1.

V. Claims 51-54, 100 and 110-112, drawn to an isolated polynucleotide comprising residues 1-755 of SEQ ID NO: 10 operably linked to a nucleic acid sequence encoding at least one regulator of morphology, and dimorphic fungal cells containing said polynucleotide, classified in class 536, subclass 24.1.

VI. Claims 55-58 and 101, drawn to an isolated polynucleotide comprising residues 1-927 of SEQ ID NO: 13 operably linked to a nucleic acid sequence encoding at least one regulator of morphology, and dimorphic fungal cells containing said polynucleotide, classified in class 536, subclass 24.1.

VII. Claims 59-62, 102 and 108-109, drawn to an isolated polynucleotide comprising residues 1-419 of SEQ ID NO: 14 operably linked to a nucleic acid sequence encoding at least one regulator of morphology, and dimorphic fungal cells containing said polynucleotide, classified in class 536, subclass 24.1.

VIII. Claims 75, 78 and 79, drawn to a generic isolated polypeptide capable of regulating the morphology of a dimorphic fungal cell, classified in class 530, subclass 300.

IX. Claim 76, drawn to an isolated polypeptide comprising SEQ ID NO: 2 or fragments or variants thereof, classified in class 530, subclass 350.

X. Claim 77, drawn to an isolated polypeptide comprising SEQ ID NO: 12 or fragments or variants thereof, classified in class 530, subclass 350.

XI. Claim 120, drawn to a method for regulating the morphology of a recombinant fungal cell, classified in class 435, subclass 440.

XII. Claim 121, drawn to a method for obtaining a predetermined dimorphic shift in a recombinant fungal cell, classified in class 435, subclass 476.

XIII. Claim 122, drawn to a method for increasing the filamentation of a recombinant fungal cell, classified in class 435, subclass 480.

XIV. Claim 123, drawn to a method for increasing the secretory capacity of a recombinant fungal cell, classified in class 435, subclass 41.

XV. Claim124, drawn to a method for producing a gene product in a recombinant fungal cell, classified in class 435, subclass 69.1.

Claim 1 link(s) inventions I-VII. Claims 40 and 85 link(s) inventions I and IV-VII. Claim 83 link(s) inventions I, V and VII. Claim 75 links inventions VIII-X. The restriction requirement regarding the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in Groups II-VII, IX and X are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such sequences to be claimed in a single application. Under this policy, a single independent and distinct sequence will be examined in a single application. The sequences are considered to be unrelated since each sequence claimed is structurally and functionally independent and distinct for the following reasons: each sequence constitutes a chemically distinct molecule, wherein the particular chemical structure is responsible for the function of the molecule. Furthermore, each individual sequence requires a separate search based on the individual nucleotide sequence (II-VII) or amino acid sequence (IX and X), thus a search of more than one (1) of the sequences claimed presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination, and the restriction groups are set forth above based on the individual sequences. This is NOT an election of species, but rather a restriction of patentably distinct inventions.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, each invention has separate utility such as a molecular probe to identify orthologous sequences in different organisms. For example, the sequence of

Group II (representing the polynucleotide encoding the PKAR protein from *Mucor circinelloides*) can be used to identify PKAR genes in other organisms. See MPEP § 806.05(d). Furthermore, the sequences of each subcombination are chemically distinct molecules that are considered separate inventions as set forth above. Regarding claims 108-112, these claims represent particularly claimed combinations of the subcombinations set forth in Groups I-VII, and are placed into a Group based upon a given subcombination sequence (i.e., claims 108 and 109 are placed into Group VII based on the presence of the patentably distinct sequence of SEQ ID NO: 14, whereas claims 110-112 are placed into Group V based upon the presence of the patentably distinct sequence of SEQ ID NO: 10). This placement is based on the rationale that if the particular subcombination sequence is free of the prior art, any combination comprising said subcombination is also free of the prior art. However, the combination being free of the art does not necessarily result in the subcombinations being free of the prior art. Because each individual subcombination is a patentably distinct invention, and only a single sequence will be searched as per the restriction requirement, the combination will only be searched in terms of the particular subcombination of the group in which it is placed, if that group is elected for examination. It is also noted that Group I contains the linking claims 1, 40, 83 and 85.

Inventions VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Specifically, Groups VIII-X relate to different amino acid sequences that are responsible for the particular biochemical functions of each polypeptide.

Because each group represents different amino acid sequences, they represent patentably distinct inventions. It is also noted that Group VIII contains the linking claim 75.

Inventions Groups XI-XV are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different effects and are not disclosed as capable of being used together. Specifically, each Group comprises different method steps that result in a different outcome. For example, Group XI contains a method step that regulates the morphology of a fungal cell, and this method step is not present in the methods of Groups XII-XV. The same is true for Group XII having a method for obtaining a pre-determined dimorphic shift, Group XIII having a method step to increase filamentation, Group XIV having a method step for increasing secretion, and Group XV having a method step for producing a gene product. Because each group has a method step that is not present in any of the other methods, the Groups have different modes of operations and effects and are therefore patentably distinct inventions.

Inventions Groups I-VII and VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions and are not disclosed as capable of being used together. Specifically, Groups I-VII relate to polynucleotide sequences whose

function is to encode or control the expression of proteins, whereas Groups VIII-X are directed to polypeptide sequences whose function is to perform a particular biological process. Thus, Groups I-VII and Groups VIII-X have distinct structures with distinct functions, and are therefore patentably distinct from each other.

Inventions Groups I-VII and XI-XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in materially different processes (such as any of the patentably distinct methods of Groups XI-XV), and the processes can be practiced with materially different products (such as any of the patentably distinct methods of Groups I-VII).

Inventions Groups VIII-X and XI-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and are not disclosed as capable of being used together. Specifically, the methods of Groups XI-XV use polynucleotide sequences, whereas Groups VIII-X are not directed to polynucleotide sequences, and thus cannot directly be used in the method steps of Groups XI-XV. As such, the different Groups have different modes of operation, and are therefore patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, especially in instances where the classifications are the same, the non-patent literature searches required for each of these inventions are not co-extensive, hence said searches would be burdensome. This is particularly relevant with regard to the different polynucleotide and polypeptide sequences of Groups I-X, which require completely different, and therefore burdensome, non-patent literature searches. Therefore restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction

requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JAMES KETTER
PRIMARY EXAMINER